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Re-evaluation Decision RVD2012-06

Denatonium Benzoate

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Re-evaluation Decision for Denatonium Benzoate

After a re-evaluation of the animal repellent denatonium benzoate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing denatonium benzoate for the sale and use in Canada.

An evaluation of available scientific information found that products containing denatonium benzoate do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of denatonium benzoate uses, new risk reduction measures must be included on product labels. No additional data are required at this time.

The regulatory approach regarding the re-evaluation of denatonium benzoate was first presented in Proposed Re-evaluation Decision PRVD2011-15, *Denatonium Benzoate*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of denatonium benzoate and summarizes the Agency's decision as well as the reasons for it. No comments were received during the consultation period. This decision is consistent with the proposed re-evaluation decision as stated in PRVD2011-15. To comply with this decision, registrants of denatonium benzoate products will be informed of the specific requirements affecting their product registration(s) and the regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-15, *Denatonium Benzoate*.

What is Denatonium Benzoate?

Denatonium benzoate is an animal repellent that is primarily used to control wild and domestic animals from feeding on trees, shrubs and other non-food woody plants. It acts as a bittering agent and deters animals such as deer from chewing on treated plants and outdoor household items due to its extremely bitter and unpleasant taste. In the end-use products, denatonium benzoate is formulated as a liquid solution or suspension which is applied via hand-held spray equipment.

Health Considerations

Can Approved Uses of Denatonium Benzoate Affect Human Health?

Denatonium benzoate is unlikely to affect your health when used according to the label directions.

Exposure to denatonium benzoate may occur when applying the product or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. Denatonium benzoate was of moderate acute toxicity to laboratory animals exposed via the oral route, but is extremely bitter and unlikely to be ingested in any appreciable amount by humans. It was of low acute toxicity to animals exposed by either the inhalation or dermal route. Denatonium benzoate was not irritating to the eyes or skin and is not considered to be a skin sensitizer. The available data indicate that denatonium benzoate does not damage genetic material and does not represent a carcinogenic concern.

The available database was sufficient to conclude that there is a very low level of concern for the hazard following exposure to denatonium benzoate and a quantitative risk assessment was not required.

Residues in Water and Food

Dietary risks from food and water are not of concern.

There are no direct food or feed uses registered in Canada for denatonium benzoate. Dietary risk to humans is not likely to be of concern based on the registered use pattern.

Non-Occupational Risks from Denatonium Benzoate

Non-occupational risks are not of concern.

Dermal, inhalation and incidental oral exposure to denatonium benzoate in residential settings are not likely to be of concern when the product is used according to label directions.

Occupational Risks from Handling Denatonium Benzoate

Occupational risks are not of concern.

Occupational exposure to individuals loading, applying and performing post-application activities are not likely to be of concern when the product is used according to label directions.

Precautionary and hygiene statements on the label (for example, wearing of personal protective equipment) are considered adequate to protect individuals from any unnecessary risk due to occupational exposure. Label statements are required to be standardized for all products to ensure consistency.

Environmental Considerations

What Happens When Denatonium Benzoate is Introduced Into the Environment?

Denatonium benzoate is not mobile and does not pose a potential risk to terrestrial and aquatic organisms.

Denatonium benzoate is used in Canada as a repellent, and it is applied to deter animals from feeding on treated plants. Denatonium benzoate is a soluble chemical that is not expected to volatilize. Phototransformation and hydrolysis are not significant routes of transformation. Biotransformation rates are unknown. However, biotransformation studies in soil and water were waived by the PMRA with the rationale that there is negligible potential exposure to the environment. It is not mobile in soils and soil column leaching studies indicate that it is not expected to leach significantly in soil. The only known transformation product is lignocaine, which was obtained during hydrolysis at low pH, but its fate in the environment has not been characterized.

When denatonium benzoate is used for repelling animals from plants, there is a very low potential that sensitive terrestrial and aquatic species will be exposed. In Canada, only pump sprayers (back pack, hand pump or mechanical pump sprayers) are allowed for its use which

limits the exposure to small areas. The risk assessment with available data indicates that denatonium benzoate presents negligible risk to fish, amphibians and aquatic invertebrates. For birds, the risk from consuming food sources contaminated during application is expected to be negligible based on the limited use pattern. Birds are not expected to consume food sources (such as leaves or tree bark) that are directly sprayed with denatonium benzoate. Negligible risk is expected for mammals since denatonium benzoate has a very bitter taste and is applied as a repellent for mammals. There are no toxicity data available on terrestrial invertebrates, but based on the use pattern, the potential exposure is expected to be limited. Therefore, no additional data are required at this time.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of denatonium benzoate, the PMRA is requiring further risk reduction measures be included on product labels.

Human Health

- A statement clarifying that the product is only for outdoor use and;
- Standardize statements for personal protective equipment and restricted entry interval for all domestic product labels.

Environment

- Standard statements for avoiding drift and contamination of water supplies for all commercial product labels.

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[5] regarding this decision on denatonium benzoate within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Denatonium Benzoate

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products in Canada must be amended as follows:

I) The following statement must be included in a section entitled **PRECAUTIONS**.

For Commercial and Domestic products:

For outdoor use only.

II) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

For Commercial products:

Avoid application of this product when winds are gusty.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT apply by field sprayer or by air.

DO NOT apply to fruit bearing trees.

Buffer zones:
Use of hand-held or backpack sprayers and spot treatments DO NOT require a buffer zone.

III) To standardize label statements, the following statements must be included in a section entitled **PRECAUTIONS** to the domestic product Registration Number 24456:

Wear chemical resistant gloves when handling product or contaminated equipment.

Do not enter treated area until spray has dried.